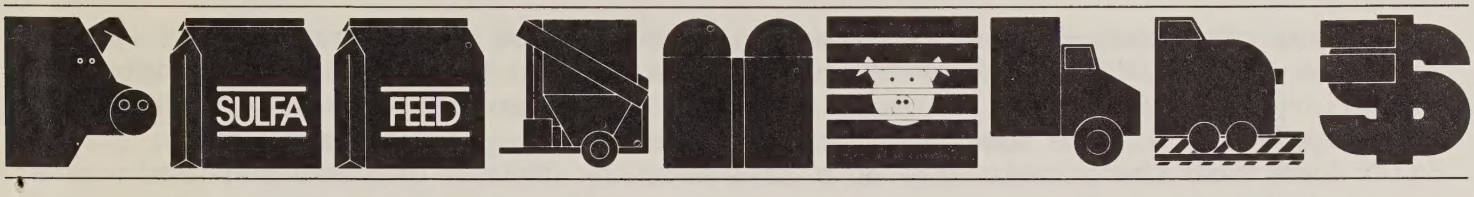
FACTS ABOUT SULFONAMIDE (SULFA)



What's the Problem?

Since the 1950's pork producers have used sulfa compounds to help control such diseases as atrophic rhinitis, pneumonia and dysentery in swine. However, in recent years the widespread use of these sulfa compounds has resulted in an unacceptable level of sulfa residues in some hog carcasses at time of slaughter.

Under the Food, Drug and Cosmetic Act--administered by the U.S. Food and Drug Administration (FDA)--it is illegal to ship to slaughter plants engaged in interstate commerce animals containing drug residues above established tolerances.

Similarly, under the Federal Meat Inspection Act--administered by the U.S. Department of Agriculture's Food Safety and Quality Service (FSQS)--meat is considered adulterated and cannot be sold for human consumption if it contains residues above the tolerances set by FDA.

Why the Concern?

As part of an expanding residue monitoring program covering various drugs, pesticides and other chemicals, USDA meat inspectors began checking hog carcasses in slaughtering plants for sulfa residues in 1973. Since then, the annual rate of violative levels of sulfa found in hog carcasses has consistently fluctuated between 10 and 15 percent of the carcasses tested. The sulfa drug identified in almost every case is sulfamethazine.

It has been difficult for producers and government officials to trace the exact causes of these residues. Initially, it was felt that lack of attention of withdrawal times and/or careless on-the-farm management practices were the major causes. Recent data, however, indicate that residues are not entirely the fault of the producer.

Some producers had stated this position earlier. For instance, residues can occur because of the use of feed that was inadvertently contaminated with sulfa and fed to swine as feed supposedly free of sulfa. As little as a quarter of a teaspoon of sulfamethazine per ton of withdrawal feed can cause violative residues in market swine. Or, residues can occur because of the recycling of sulfa through the ingestion that occurs when swine are exposed to manure and urine.

United States Department of Agriculture · Food Safety and Quality Service
Science and Education Administration · Animal and Plant Health Inspection Service

Health experts, consumers and producers' representatives are concerned about excessive levels of drug and other chemical residues in their food. Some people are allergic to certain sulfa drugs. So even very low amounts of sulfa in the food supply could cause some allergic reactions in some people. Some authorities have said there could also be a risk that low amounts of sulfa consumed over a long period of time may cause resistance to therapeutic treatments for the use of sulfa if it became necessary.

Despite previous efforts by the government and the pork industry to reduce these sulfa residue levels, the problem persists. Action is now being taken that should permit swine producers to continue using these drug compounds... eliminate a potential human health risk...and help consumers maintain confidence in the wholesomeness of pork.

How Are Tolerances Set?

Before FDA can approve a drug for use in food-producing animals, the drug manufacturer must submit toxicity data showing the drug will be safe for use in the animal at recommended levels. If at these levels a residue is left in the meat, a tolerance must be established. A withdrawal time is then prescribed, if necessary, to assure the drug will be reduced to the acceptable level.

The current FDA tolerance for sulfa in pork is 0.1 parts-per-million (ppm). This tolerance is based on 90-day toxicity studies in rats and dogs and is designed to provide a 2,000-fold safety margin for humans. FDA recently recommended against raising this tolerance, because it did not have sufficient toxicological data to justify lowering the margin of safety for humans.

New toxicity studies would have to be conducted by sulfa drug manufacturers to show that a higher tolerance would be safe. Such studies are costly and could take 2 to 3 years to complete.

What About Withdrawal Times?

FDA establishes withdrawal times for drugs fed to food-producing animals--i.e., the number of days prior to slaughter during which the drug cannot be fed to the animal. FDA recently lengthened the withdrawal time for sulfamethazine to 15 days. This action was based on the continuing high rate of sulfamethazine residue violations, and recent data showing that the previous withdrawal times of 5-10 days did not provide the necessary margin of safety to assure that hogs going to slaughter would be free of illegal sulfa residues.

Whose Hogs Get Sampled?

Sulfa is just one of many drugs and chemicals for which FSQS meat inspectors take samples for laboratory testing. The FSQS monitoring program is based on

a computerized plan for random sampling, so that laboratory findings will be a statistically valid representation of all swine slaughtered nationwide.

No one can predict if or when a certain producer's hogs will be sampled. The computer determines the specific plant and day the inspector is to take tissue samples from hog carcasses for sulfa and other residue tests. Approximately 500-650 samples are taken each month.

After an inspector takes a sample from a carcass, the sample is frozen and shipped to an FSQS laboratory. The initial tests on that sample to determine if sulfa residues are present require about 5 working days. If a residue is detected, it requires an additional working day to confirm its presence and amount.

FSQS labs are using the most advanced, approved analytical testing procedures, including mass spectrophotometry, thin layer chromotography (TLC), gas liquid chromotography (GLC) and the Tischler modification of the Bratton-Marshall test.

What Happens When Residues Are Found?

When sulfa residues above the tolerance level are found, the producer is contacted by FSQS and advised that violative levels have been detected. Under the special sulfa residue action plan now underway, the producer is also contacted by a USDA representative and offered help to pinpoint the cause of the residue and identify appropriate steps to resolve the problem.

The producer must then make a choice: (1) Send future hogs to market and have them retained at the slaughter establishment until they are tested and found free of violative residues; or (2) send a sample lot of five hogs to slaughter for "pre-market" testing. Regardless of which choice is selected, the producer must demonstrate that future hogs will not have above-tolerance sulfa levels before FSQS can accept them through normal channels. Either way, the producer's normal production and marketing operations are disrupted, and he or she loses money.

If the present problem is not corrected, there is a probability that the approval of sulfa compounds for use in swine feeds will be withdrawn. This would be costly to producers who depend on sulfa compounds for increased feed efficiency and would indirectly result in higher pork prices to the consumer.

What's Being Done to Help The Industry?

To avoid more drastic action, USDA and FDA--in cooperation with all segments of the swine industry--have launched a special sulfa residue action plan aimed primarily at reducing numbers of sulfonamide residue violations. This special campaign--to be carried out through September 1979--consists of three phases:

--On-farm survey: An initial survey was conducted in May 1978 to better identify the most common sources of sulfa residues. The results of that survey are now being used to help producers whose hogs have been found to have above-tolerance residues in solving their individual problem.

--Expanded information/education campaign: The responsible USDA agencies, FDA, state Extension services, state departments of agriculture, producers' organizations, feed manufacturers, drug firms, veterinarians, marketing agencies, and other concerned groups are working together to make sure that everyone connected with pork production knows what to do to help eliminate above-tolerance residues.

--Stepped up research: A lot of "unknowns" still exist on the causes of residues, and what must be done to avoid residues. So, more research is being undertaken to find the needed answers. These studies are being undertaken through USDA and cooperating organizations and state research facilities.

What Can You Do Now?

If you use sulfa drugs now, especially sulfamethazine, or are considering their use, here are some of the things you should do:

*Know precisely what ingredients are being used in your feed, and keep samples of each lot of feed and/or separate ingredients. Label and date these samples;

*Clearly label and keep sulfa-medicated feeds separate from other medicated and non-medicated feeds during mixing, storage and feeding;

*Consult your feed supplier to be sure he is separating medicated and non-medicated feed when mixing, storing and delivering;

*Follow or exceed the recommended withdrawal time before sending hogs to market;

*Thoroughly clean all pens, feed troughs, watering systems, etc., when sulfa is withdrawn. Clean pens again 72 hours after withdrawing sulfa;

*Do not allow hogs receiving medicated feeds to mix with those not on medication;

*Cease feeding sulfonamides to hogs in accordance with label directions;

Take time now to learn more about how residues can occur and the steps you should take to avoid them.

The time you take today may save you money tomorrow.

# # # #